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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,559	08/25/2003	Brian M. Holmes	B0077-US01	5159

24994 7590 11/22/2005

GAMBRO, INC  
PATENT DEPARTMENT  
10810 W COLLINS AVE  
LAKEWOOD, CO 80215

EXAMINER
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REIFSNYDER, DAVID A

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 11/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/648,559

Applicant(s)

HOLMES ET AL.

Examiner

David A. Reifsnyder

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 August 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-19 and 48-55, drawn to an apparatus for centrifugally separating a volume of a composite fluid into first and second fluid components, classified in class 210, subclass 143.
- II. Claims 20-29, drawn to a method for centrifugally separating a composite fluid into first, second and third fluid components, said components having different densities, classified in class 494, subclass 37.
- III. Claims 30-42, drawn to a set of containers comprising a separation container connected to a fluid component collection container, classified in class 210, subclass 257.1.
- IV. Claims 43-47, drawn to a device for loading a set of bags into the rotor of a centrifuge, classified in class 210, subclass 232.

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the instantly claimed process can be practiced by a materially

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different apparatus such as one does not include a sensing means (i.e. sensor), squeezing means (i.e. squeezing member) or control means (i.e. control unit).

Inventions I and III are unrelated. Invention I is drawn to an apparatus comprising, valve members, squeezing members, sensors a control unit while Invention III is drawn to a set of containers comprising a separation container connected to a fluid component collection container, the separation chamber comprising an annular chamber and a distribution channel attached to the annular chamber (see MPEP § 806.04, MPEP § 808.01).

Inventions I and IV are unrelated. Invention I is drawn to an apparatus comprising, valve members, squeezing members, sensors a control unit while Invention IV is drawn to a device for loading a set of bags into the rotor of a centrifuge, said device comprising a loading container having an annular rim and said container being shaped so as to fit within the compartment of the rotor. (see MPEP § 806.04, MPEP § 808.01).

Inventions II and III are unrelated. Invention II is drawn to a method for centrifugally separating a composite fluid into first, second and third fluid components, said components having different densities, said method comprising: transferring the composite fluid into a separation chamber connected to a two component containers; spinning the separation container so as to separate the first, second and third fluid components; transferring at least a major portion of the first separated fluid component to one of the fluid component containers; and transferring either the second or third fluid component to the other one of the fluid component containers while Invention III is

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drawn to a set of containers comprising a separation container connected to a fluid component collection container, the separation chamber comprising an annular chamber and a distribution channel attached to the annular chamber (see MPEP § 806.04, MPEP § 808.01).

Inventions II and IV are unrelated. Invention II is drawn to a method for centrifugally separating a composite fluid into first, second and third fluid components, said components having different densities, said method comprising: transferring the composite fluid into a separation chamber connected to a two component containers; spinning the separation container so as to separate the first, second and third fluid components; transferring at least a major portion of the first separated fluid component to one of the fluid component containers; and transferring either the second or third fluid component to the other one of the fluid component containers while Invention IV is drawn to a device for loading a set of bags into the rotor of a centrifuge, said device comprising a loading container having an annular rim and said container being shaped so as to fit within the compartment of the rotor. (see MPEP § 806.04, MPEP § 808.01).

Inventions III and IV are unrelated. Invention III is drawn to a set of containers comprising a separation container connected to a fluid component collection container, the separation chamber comprising an annular chamber and a distribution channel attached to the annular chamber while Invention IV is drawn to a device for loading a set of bags into the rotor of a centrifuge, said device comprising a loading container having an annular rim and said container being shaped so as to fit within the compartment of the rotor. (see MPEP § 806.04, MPEP § 808.01).

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The inventions are distinct, each from the other because of the following reasons:

This application contains claims directed to the following patentably distinct species of the claimed invention:

Species	Number of Centrifugation Speeds	Claim Numbers
I	Two	20-28
II	One	29

If the applicant elects Invention II, than the applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, none of the claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for all the inventions is different, restriction for examination purposes as indicated is proper.

A telephone call was made to John R. Merking on November 18, 2005 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


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**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Reifsnyder whose telephone number is (571) 272-1145. The examiner can normally be reached on M-F 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda M. Walker can be reached on (571) 272-1151. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
David A Reifsnyder  
Primary Examiner  
Art Unit 1723

DR